IVDMIA: Comment from the Association for Molecular Pathology

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About AMP

- AMP is dedicated to the advancement, practice, and science of clinical molecular laboratory medicine and translational research based on the applications of genomics and proteomics.
- >1,400 molecular pathology professionals
- Diverse group from different backgrounds

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AMP Supports IVDs

AMP supports the development of tests and test systems for *in vitro* diagnostic use and encourages industry to pursue FDA clearance and approval where current regulations require.

AMP Questions FDA Interest in Regulating Transparent Algorithms

- Medical algorithms using patient information have long been used, *e.g.*
  - Tumor classification
  - Serum glucose in context of time of last meal
- Many algorithms are published with peer review and are available for professional scrutiny
- The algorithms are constantly being evaluated and updated

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Broad Language of Concern

- Future interpretation could extend far beyond current intended reach
- Harmful potential for patient care
  - Severely reduce availability of tests
  - Compromise quality of tests
  - Reduce physician's ability to manage care
  - Limit patient access to new or improved tests
- Tests that could be included:
  - Expanded maternal serum screening
  - Bayesian calculation for cystic fibrosis

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IVDMIA Definition Developed Outside of Rulemaking Process

- Proposed definition makes laboratories the manufacturer of medical devices, subject to FDA regulation.

- This area of lab operation is regulated currently by CMS under CLIA

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AMP Recommendations

AMP respectfully requests that…

FDA Provide Scientific Rationale

FDA provide the scientific rationale for their new concerns over the safety and effectiveness of laboratory-developed tests, as well as a justification for their jurisdiction over medical testing algorithms.

External Classification Panel

FDA convene a classification panel (*e.g.,* as was done in the reclassification of immunohistochemistry tests) so that criteria for determining which tests will be subject to FDA regulation will be transparent to laboratories developing such tests.

Publish a List of IVDMIAs

FDA clearly and specifically define the scope of IVDMIAs that it intends to regulate.

Regulation from Appropriate Agency

FDA ensure that any new guidance does not insert FDA into the purview of CMS regulation of laboratories under CLIA.

Non- “Black Box” Products ASRs

FDA apply restrictions requiring PMA or 510(k) clearance of an IVDMIA only when the interpretive algorithm remains undisclosed by the manufacturer.

Clarify Criteria That Labs Must Meet as Device Manufacturers

FDA clarify the scope of its regulations that renders laboratories responsible for meeting criteria as medical device manufacturers, *i.e.*, pre-market review only or all general controls (registration and listing, quality systems, labeling, medical device reporting).

Thank You